



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/509,934 | 05/03/2000 | ANDREAS STEINMEYER | SCH1747 | 6707 |

7590 02/24/2004

MILLEN WHITE ZELANO & BRANIGAN
ARLINGTON COURTHOUSE PLAZA I
2200 CLARENDON BOULEVARD
SUITE 1400
ARLINGTON, VA 22201

EXAMINER

QAZI, SABIHA NAIM

ART UNIT PAPER NUMBER

1616

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/509,934 | Applicant(s) STEINMEYER ET AL. | |
| | Examiner Sabiha N. Qazi | Art Unit 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-3,5,6 and 8-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-3,5,6,14 and 20-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 8-13 and 15-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>7/1/03</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Office Action

This Application is a 371 of PCT/EP 98/06159 that claims priority of a German Application filed on 9/29/1998.

Presently claimed invention is drawn to vitamin D compounds with a cyclopropyl substituted side chain and includes 19-nor vitamin D compounds.

Acknowledgement is made of the response filed on 10/14/03. Arguments are found persuasive in part therefore; groups II and VIII are combined. Method of use claims will be joined when the compounds would be allowed in a condition that they have full support in the disclosure. For such a broad claim encompassing thousands of compounds (the invention includes 19-nor vitamin D compounds) there must be a solid support for method of use claims. Claims 1-3, 5, 6, and 8-35 are pending. No claim is allowed at present time. Claims 8-13 and 15-19 are withdrawn from consideration as non-elected invention. Claims 1-3, 5, 6, 14 and 20-35 are rejected.

Lack of unity exist in claims because compounds, corresponding compositions and method of use that are of the scope are considered to form a single inventive step as required by PCT Rule 13.1, 37 CFR 1.475(d). Claims are not so linked as to form a single inventive step concept. Applicant attention is drawn to for example claims 12 and 13, which are intermediates and do not form a single inventive step according to PCT Rules. Claim 19 is independent claim this claim will be joined with claim 1 when it will be dependent on claim 1.

Since it had been a long prosecution Applicant cooperation is necessary, it is suggested that claims should be amended to a reasonable genus at this time. Examiner notes, that Applicants do not amend claims in such a long prosecution but added claims most of the time with the response.

In order to advance the prosecution Examiner called several times this week to discuss the possible amendments. Unfortunately Mr. Heaney was not available to the Examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5, 6, 14 and 20-35 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over United States Patent No. 6,372,731 (KIRSCH et al.). The reference teaches vitamin D derivatives of formula 1, which embraces presently claimed invention.

The prior art of record is drawn to structurally similar compounds, which differ, from the compounds embraced by the instant claims in that they are homolog. See compounds 6a, 6b, 7b and 8b in Fig. 1; compound 9b, 15b in Fig. 2; compound 16b, and 18b in Fig. 3; compound 27a, and 27b in Fig. 5; compounds 33a to 43a and 33b to 43b in Fig. 6; compounds 55a-70a and compound 55b to 70b in Fig. 8; compound 116b, 117b in Fig. 13 and others.

All these specific compounds disclosed in the reference differ from the presently claimed invention that Q is not CHOH. However, Q can be CH₂-CHOH, or CH₂-CH₂-CHOH (see present claim 3), which is a homolog of the compound, which is disclaimed.

The skilled artisan would have been motivated to modify the teaching of the prior art to prepare homologs because it is recognized in the art that homologs are structurally similar and would be expected to possess similar properties. *Ex parte Henze* (POBA 1948) 83 USPQ 167.

Compounds that differ only by the presence of an extra methyl group are homologues. Homologues are of such close structural similarity that the disclosure of a compound renders prima facie obvious its homologue.

The homologue is expected to be synthesized by the same method and to have the same properties i.e. useful for the treatment of osteoporosis and hyperthyroidism. This expectation is then deemed the motivation for preparing homologues. See *In re Wood* 199 USPQ 137; *In re Hoke* 195 USPQ 148; *In re Lohr* 137 USPQ 548; *In re Magerlein* 202 USPQ 473; *In re Wiechert* 152 USPQ 249; *Ex parte Henkel* 130 USPQ 474; *In re Fauque* 121 USPQ 425; *In re Druey* 138 USPQ 39.

In all of these cases, the close structural similarity of two compounds differing by only one (or two) methyl groups sufficed; no specific teaching to methylate was present or required.

In absence of any criticality of the invention and/or unexpected results presently claimed invention is considered obvious over the KIRSCH et al. reference.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on every business day..

Application/Control Number: 09/509,934
Art Unit: 1616

Page 5

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Sabiha N. Qazi

Primary Examiner

Art Unit 1616